

Structured Product Labeling (SPL) OTC Sub-team Teleconference

Monday, February 23, 2009, 1:00 pm – 2:30 pm ET

Call Summary

I. Welcome and Introductions

Call included approximately 20 SPL OTC sub-team members and guests.

II. Next Standing Teleconference: March 9, 2009, 1:00 – 2:00 pm ET (unless cancelled)

Please send any agenda topics to sub-team leaders Paula Markert (GSK), Devon Morgan (Perrigo), and liaison Marcia Howard (CHPA) at your convenience.

III. Implementation Date of June 1, 2009

There was a discussion about whether or not the June 1, 2009, implementation date is established by regulations and/or statute. The date is referenced in the guidance documents which are recommendations from the Agency. Additional clarification will be sought from FDA regarding the date as well as what procedure FDA will follow for any paper submissions made after June 1.

IV. SPL Submission of the Principle Display Panel (PDP) Information

Several questions regarding what info is needed for OTC PDP submissions posed to FDA but additional clarification of the responses may be needed. The questions and answers are provided below (I have left the questions in the original manner in which they were stated to provide context).

Questions:

I have a question. On the slide enclosed from the FDA slide deck that was used during the FDA OTC Overview a couple of months ago, it had a breakdown of the pieces of the SPL for OTC. It showed the "principal display panel" which I think is a graphic but it was called "principal display panel text".

Do you know if we will need to add the text from the display panel as a separate part of the SPL or will the SPL just have the graphic of the principal display panel ? I am not sure what they mean by "text". And then how does the principal display panel differ from the carton/bottle label ?

Responses:

See section 4.7 of the Instructions for using the SPL Xforms document for information regarding the inclusion of the text of the principal display panel.
http://www.fda.gov/oc/datacouncil/SPL_r4_XForms_instructions_v1.0.pdf

The definition for principal display panel is in the regulations: (21 CFR 201.60)
<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=201.60>.

Further clarification will be sought from FDA but generally, the PDP is provided as a jpg file with the electronic submission. Drug Facts (DF) and PDP information is what the agency needs. The entire carton (*e.g.*, outer carton) should be flattened and sent as a jpg file with the electronic SPL submission. FDA would like to collect information from the PDP that may not be contained in DF such as net content, claims, etc. which may be what is referenced as “text” from the PDP. Any additional feedback from FDA will be conveyed to sub-team members.

V. Upcoming SPL Educational Forums

FDA webinars and in-person meetings: The May 21st in-person meeting has reached capacity. SPL OTC sub-team members will be notified if additional face-to-face sessions are scheduled. A sixth webinar session, which began today, has also been arranged. Persons interested in enrolling in this session should contact FDA at SPL@fda.hhs.gov.

VI. Vendor Presentation: Data Conversion Laboratory, Inc.

The vendor presentations are provided as educational opportunities only and do not reflect any endorsement or recommendation by the SPL OTC Sub-team, SPL Process Team, SPL Leadership Team, or the FDA.

Slides from the presentation are now available at the [Wiki page](#) at the OTC sub-team site.

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Last Revised: February 23, 2009 Sent: February 23, 2009

Mass Delisting Procedures – From Generics SPL Sub-team Minutes of December 15, 2008

(please visit Wiki page for additional information)

How to mass delist prior to the date when the electronic submission of drug establishment registration and drug listing information is mandatory.

This discussion is about NDC delisting. This would be to clean up NDC lists and avoid having to submit the SPL just to have it removed.

The information the FDA needs is:

- Name of drug
- Strength & unit
- Discontinuation date (may be future dated)
- NDC Number

The above is sufficient to remove NDC numbers from the NDC database. You may put in an Excel spreadsheet with the above information and send it to: spl@fda.hhs.gov **prior to June 1, 2009.**